

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO DEFENDANTS FOREST LABORATORIES, INC. AND FOREST PHARMACEUTICALS, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. (collectively, “Forest”) (hereinafter “Forest MTD”) seek the dismissal of all claims as insufficient under Fed. R. Civ. P. 8(a) and 9(b) on the grounds that: (i) plaintiffs’ allegations do not adequately explain the fraudulent nature of the Forest spreads; (ii) plaintiffs’ allegations are insufficient to show that Forest failed to properly report Best Price; and (iii) there was no adverse finding by the government investigations cited by plaintiffs. Forest also says all claims against it were ultimately dismissed by this Court in *County of Suffolk v. Abbott Labs., et al.* (Civ. Action No. 1:03-cv-10643)(MDL 1456) (“*Suffolk*”) and should be dismissed here as well.

Forest’s arguments are incorrect. Plaintiffs allege fraudulent AWP’s for all Forest drugs for which they seek relief and properly use available market prices to demonstrate the artificially high Forest spreads. Plaintiffs also allege sufficient grounds to support their Best Price claims, including allegations relating to government investigations into Forest’s pricing practices that support plaintiffs’ claims of Best Price and AWP fraud.¹ This specificity satisfies the particularity requirements of Rule 9(b) as well as the Court’s prior rulings, including all those in *Suffolk*.² Lastly, the Court did not dismiss certain state claims against Forest in *Suffolk*, see part D below.³

DISCUSSION

A. Plaintiffs’ Fraud-Based AWP Claims Are Pled With Sufficient Particularity.

¹See Corrected Consolidated Complaint, filed on June 22, 2005 (“Consolidated Complaint” or “CC”) at ¶¶476-85, CC Exh. A & B; Nassau Second Amended Complaint, filed on January 6, 2006 (“Nassau SAC” or “NSAC”) at ¶¶385-394, NSAC Exh. A & B.

²See *In re Pharm. Indus. Average Wholesale Price Litig.* 339 F.Supp.2d 165, 173 (D. Mass. 2004)(“*Suffolk I*”); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125 (D. Mass. Oct. 26, 2004) (“*Suffolk II*”); *In re Pharm. Indus. Average Wholesale Price Litig.* Memorandum and Order, (D. Mass. April 8, 2005)(“*Suffolk III*”).

³All other causes are addressed in Plaintiffs Consolidated Opposition to Defendants’ Motion to Dismiss, filed contemporaneously herewith (referred to herein as “Consolidated MTD Opposition”).

Forest contends that plaintiffs have failed to explain how Forest's spreads are fraudulent. Forest MTD at 2-3. Forest claims that it is well-recognized that spreads exist between AWP and actual pricing, "with it being generally understood that WAC is lower than AWP." *Id.* at 2 (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 209 (D. Mass. 2004) ("*Pharm. III*"). As such, Forest contends that plaintiffs do not adequately plead the fraudulent basis of the AWPs.

The argument is remarkably superficial. To maintain fraud-based AWP Claims, plaintiffs must set forth factual allegations regarding spread, internal documents or government investigations from which an inference of fraud can reasonably be made. *See Suffolk II*, 2004 WL 2387125, at *2; *Pharm. III*, 307 F. Supp. at 209 (recognizing an industry-wide practice of inflating AWPs and not requiring a specific spread for every drug of each manufacturer). Furthermore, in alleging a spread, using a calculated actual average sales price for a drug will not suffice. *See Suffolk III* at 2.

Plaintiffs have satisfied these threshold requirements. Plaintiffs (1) provide fraudulent AWPs for all Forest products for which plaintiffs paid; (2) detail exorbitant spreads calculated based on actual available market prices⁴ -- not a calculated average price -- for Forest products;⁵ (3) show that Forest spreads for drugs paid for by plaintiffs were consistently over 66%, often over 100%; (4) allege that Forest promoted its products by marketing the spread and selling its products at substantial discounts off WAC while maintaining a false and inflated AWP; (5) allege that Forest

⁴Spreads are calculated with actual market prices offered to Ven-a-Care of the Florida Keys, Inc. ("Ven-a-Care"), a licensed pharmacy, and were available nationally to similar pharmacies. In the matter styled, *State of California ex rel. Ven-a-Care of the Florida Keys v. Abbott Labs., et al.*, also pending before this Court, the same prices were utilized to calculate the spreads in support of similar claims. The legitimacy of these prices was not questioned in recent motions to dismiss filed in that action.

⁵It is unclear whether Forest contends that the Court rejected the concept of providing a spread or that plaintiffs are using average spreads rejected previously by the Court in *Suffolk III*. *See* Forest MTD at fn 3. Regardless, both are incorrect.

was aware that its purchasers' profits depend on the reimbursement rates of Forest drugs; (6) show that Forest offered rebates through drugs suppliers in addition to upfront discounts. This had the practical effect of providing additional savings on top of contract pricing, thus increasing the reimbursement spread for the purchaser; (7) allege that the attorney generals of the States of Illinois and Kentucky are pursuing similar fraudulent AWP claims against Forest for its drug Tiazac, among others; (8) properly refer to two government investigations.⁶ See CC ¶¶476-485, Exh. A, B & F; NSAC ¶¶390-391, Exh. A&B.

The foregoing is certainly sufficient to draw a reasonable and decidedly sound inference of a company-wide AWP fraud in compliance with the requirements of Rule 9(b). See *U.S. ex rel. Franklin v. Parke Davis*, 147 F.Supp.2d 39, 49 (D.Mass 2001)(Saris, J.)("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible."). Accordingly, all of plaintiffs' fraud-based AWP claims should be sustained.

B. Plaintiffs' Fraud-Based Best Price Claims Are Pled With Sufficient Particularity.

In order to maintain Best Price claims, plaintiffs must "set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported ... for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices." *Suffolk II*, 2004 WL 2387125, at *3.

Plaintiffs have done both. First, plaintiffs identify every Forest drug for which they assert Best Price claims. See CC ¶¶476-485, Exh. A, B & F; NSAC ¶¶385 - 394, Exh. A & B. Second, plaintiffs allege a company-wide scheme and strategy whereby Forest utilized aggressive discounts and off-invoice pricing to lower prices and maximize sales. Plaintiffs allege that: (1) Forest omits from their rebate calculations cash payments, free samples, bundling of other free drugs, tying

⁶ These investigations are- the Senate Finance Committee's nominal pricing investigation and the OIG of the Office (continued...)

arrangements that are retroactive rebates, in-kind services, routine discounts (such as volume and prompt-pay discounts), rebates and other off-invoice transactions and inducements offered to create market share and demand for Forest drugs (*see* CC ¶ 22; NSAC ¶ 15); off-invoice pricing allows a manufacturer to lower the net cost to the purchaser while concealing the actual cost beneath the fiction of a higher invoice (*see* CC ¶ 153; NSAC ¶ 122); (3) Forest knew that its pricing practices directly affected its purchaser's profits; (4) Forest is subject to government investigations that are probative and directly relevant to plaintiffs' Best Price claims. Plaintiffs discuss the relevance of these investigations in Point C, *infra*. *See* CC ¶¶ 476-485; NSAC ¶¶ 385 - 394. Accordingly, all of plaintiffs' fraud-based Best Price claims should be sustained.⁷

C. The Government Investigations Provide a Reasonable Inference of Fraud to Plaintiffs' Best Price and AWP Claims.

The Court held "government investigations from which an inference of fraud [could] reasonably be made" are directly relevant to claims concerning fraudulent AWP's and related reimbursement practices. *Suffolk II*, 2004 WL2387125, at *2; *Pharm III*, 307 F. Supp.2d at 209. The Court does not require an adjudication of the lawsuits or government investigations. *See id.*

Here, the CC alleges that Forest is subject to two government investigation relevant to plaintiffs' Best Price and AWP claims: (1) the Senate Finance Committee Investigation of Nominal

of Personnel Management's investigation concerning Forest's practices for Mental Health drugs

⁷Forest erroneously alleges that Nassau County "admits that it has no evidence to support this [Best Price] claim." Forest MTD at 3. To the contrary, the Nassau SAC states, "[w]hen Forest's failure to report Best Price for these drugs is factored in, the spread between reported AWP and the true AWP will be even greater. The facts surrounding Forest's discounting and rebate activities, which affect the Best Prices for its drugs are uniquely within Forest's control at this time and will be revealed through discovery." NSAC at ¶ 388. Nassau County has not conceded that it has no evidence regarding Best Price, but rather has alleged upon information and belief that Best Price evidence exists and is within the control of Forest.

"The Rule 9(b) pleading requirement is relaxed when 'the facts underlying the fraud are peculiarly within the defendants' control.'" *United States ex rel. Karvelas. v. Melrose-Wakefield Hospital*, 2003 U.S. Dist. LEXIS 8846, at *13 (D. Mass May 21, 2003) (quoting *Franklin* 147 F. Supp. at 47 (D. Mass 2001)(internal quotations omitted)). Since the information regarding Best Price evidence is not publicly available, it is uniquely within the defendant's control. Thus, under this circumstance, fraud may be pled on information and belief. *Karvelas*, at *14. Since Nassau has met this threshold, its claims against Forest should stand.

Price Violations (“Senate Investigation”); and (2) the Office of Inspector General of the Office of Personnel Management investigation of Forest’s marketing practices for mental health drugs. CC at ¶¶484-485.

The Senate Investigation concerns potential abuses of the nominal price exception to the Best Price reporting requirements. The exception allows drug companies to exclude drug prices less than 10% of AMP from their Best Price calculations. *See* 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). The exception is intended to apply to non-commercial sales only. Many drug companies, including Forest (as alleged), fraudulently claim commercial sales as within the exception to avoid higher Best Price rebates.⁸ As such, an investigation into nominal price abuse is entirely relevant and draws an inference of fraud to Forest’s sales practices.⁹

D. The Court Previously Sustained Certain Suffolk Claims Against Forest.

Forest claims that the Court “ultimately dismiss[ed] all of Suffolk’s claims against Forest.” Forest MTD at 1. This argument is completely inaccurate and baseless.¹⁰ Thus, even if the Court finds that the pleadings have not satisfied Fed. R. Civ. P. 9(b), these claims survive. Forest does not

⁸Nominal price abuse significantly reduces Best Price rebates. For example, assume AMP is \$1.00 and Best Price is \$.87, then the rebate is the greater of: either 15%*AMP or (AMP-Best Price). Assume also that a company reports a Best Price of \$.87, and improperly claims that a nominal price transaction of \$.09 should be exempted from Best Price calculation. Thus, 15%*AMP (i.e. \$.15) is greater than AMP-best price (i.e. \$.13), the company would report a rebate of \$.15 per claim. The nominal price exception on the \$1.00 AMP is any non-commercial drug sales with prices below 10% of AMP or \$.10. If the drug company in this example improperly claims the \$.09 sale is exempt, then the rebate payment for that drug to all state Medicaid programs would increase from \$.15 to \$.91 PER UNIT SOLD, a 600% increase.

⁹Forest contends that the investigation is only a “simple inquiry” into nominal price. Forest MTD at 3. This is self-serving ipse dixit. There has been no public proclamation that Forest is absolved or cleared of any wrongdoing. The fact is that the Senate Finance Committee had a reasonable basis to investigate Forest for abuse of the nominal price exception.

¹⁰ See Consolidated MTD Opposition at Procedural History. The Court’s Suffolk III decision -- regarding whether Suffolk satisfied 9(b) with respect to the “Suffolk 13 +6” -- in no way modified either its Suffolk I or Suffolk II decisions. There, the Court sustained Suffolk’s AWP-based and Best Price-based unjust enrichment claims and claims for violation of 18 N.Y.C.R.R. §515.2(b)(4) & (5) against the Suffolk 13 +6. In Suffolk II, the Court expressly held that Rule 9(b) did not apply to these claims, as they “do not require a pleading of fraud or mistake.” (continued...)

dispute any non-fraud related claims.

CONCLUSION

For the reasons set forth herein, all claims against Forest should be sustained.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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